UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,675	01/29/2004	Tom McHale	S63.2-10813US01	5432

490 7590 12/21/2010

VIDAS, ARRETT & STEINKRAUS, P.A.
SUITE 400, 6640 SHADY OAK ROAD
EDEN PRAIRIE, MN 55344

EXAMINER	
SEVERSON, RYAN J	
ART UNIT	PAPER NUMBER
3731	

MAIL DATE	DELIVERY MODE
12/21/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/767,675	MCHALE ET AL.	
	Examiner	Art Unit	
	RYAN J. SEVERSON	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 October 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26 and 58-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26 and 58-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. **Claims 1, 5, 6, 12, 13, 15, 17-20, 59 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nobuyoshi et al. (5,250,069) in view of Ehr et al. (6,398,709).** Regarding claim 1, Nobuyoshi et al. disclose a catheter comprising a catheter shaft (1) having an inflation balloon (3) having proximal and distal waist portions, proximal and distal cone portions, and a main body portion (see figure 1). The catheter has a catheter tip (the portion of tube 1 that extends beneath the balloon and distal of the balloon) having a guidewire lumen (4). However, Nobuyoshi et al. fail to disclose first and second recessed portions on the catheter tip. Attention is drawn to Ehr et al., who teach the concept of having proximal and distal recessed regions (50 and 50') on an intraluminal medical device (see figure 16) that surround a central shaft portion (124) to provide increased flexibility to the device (see column 4, lines 33-36). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have created recessed regions bordering a central shaft portion on the catheter tip of Nobuyoshi et al. in the manner taught by Ehr et al. to increase the flexibility of the tip at the points where the shaft is recessed.

3. Ehr et al. disclose the central shaft portion (124) has the same diameter as the proximal and distal portions of the shaft on the opposite sides of the recessed portions (see column 6, lines 14-16). One having ordinary skill in the art would have recognized the recessed portions could be oriented beneath the conical portions (see paragraph 23 below for evidence to support this assertion).

4. Regarding claim 5, the catheter distal tip of Nobuyoshi et al. is radiused (see figure 1).

5. Regarding claim 6, one having ordinary skill in the art would have recognized the recessed portions could be oriented beneath the conical portions.

6. Regarding claims 12 and 13, Nobuyoshi et al. disclosed a spring stiffener (13).

7. Regarding claim 15, the tip has first and second regions, where the second region (i.e. at the location of the stiffener, see figure 1) is less flexible than the first region (i.e. at the location of the recessed portions).

8. Regarding claim 17, the catheter further includes an outer catheter shaft (2) with the balloon proximal waist portion coupled to said outer shaft (see figure 1).

9. Regarding claims 18-20, it has been held that even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

10. Regarding claim 59, the second region (as set forth with respect to claim 15) has stiffening fibers that are polypropylene (see column 7, lines 1-5).

11. Regarding claim 60, the balloon main body portion is cylindrical (see figure 1).

12. **Claims 2-4, 7-10 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nobuyoshi et al. (5,250,069) in view of Ehr et al. (6,398,709) as applied to claim 1 above, and further in view of Fulton (6,074,374).** The combination of Nobuyoshi et al. and Ehr et al. fails to disclose a marker or hub disposed beneath the balloon. Attention is drawn to Fulton, who teaches a marker or hub (69) is disposed beneath the balloon to allow the balloon to be place in the body in the correct place (centered at the treatment site) using well-known visualization techniques. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the marker hub of Fulton on the shaft beneath the balloon of the combination of Nobuyoshi et al. and Ehr et al. to allow the correct placement of the catheter and balloon at the treatment site.

13. **Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nobuyoshi et al. (5,250,069) in view of Ehr et al. (6,398,709) and Fulton (6,074,374) as applied to claim 9 above, and further in view of Follmer et al. (5,728,065).** The combination of Nobuyoshi et al., Ehr et al., and Fulton fails to disclose a marker disposed flush with the outer surface of the catheter tip. Attention is drawn to Follmer et al., who teach a radiopaque marker (124) insert molded flush with the tip (see figure 2) to create a tip that has a low profile and can be imaged because the marker does not project radially outwardly from the tip. Therefore, it would have been obvious to one of

ordinary skill in the art at the time the invention was made to insert mold flush the marker of Follmer et al. with the tip of the combination of Nobuyoshi et al., Ehr et al., and Fulton to create a tip that has a low profile yet can be located and guided using conventional imaging techniques.

14. **Claims 16 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fulton (6,074,374) in view of Nobuyoshi et al. (5,250,069).** Fulton discloses a catheter comprising a catheter shaft (61), a balloon (64), and a catheter tip having a recessed portion (67) oriented beneath the balloon. The tip further includes a proximal end (at the left side of figure 3), a distal end (71), a main shaft portion (61), and a distal shaft portion (at 65 in figure 3). The catheter has a first region (the recessed portion) that is more flexible than the second region (the main shaft portion proximal of the recessed portion) because of the reduced size. However, Fulton fails to disclose entrained stiffening fibers that are polypropylene or polyolefin. Attention is drawn to Nobuyoshi et al., who teach entrained stiffening fibers (13, see figure 1) of polypropylene (see column 7, lines 1-5) to stiffen the catheter. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have included entrained stiffening fibers in the second region of the shaft of Fulton in the manner taught by Nobuyoshi et al. to provide stiffness to the second region.

15. Regarding claim 58, the tip has first and second recessed portions (i.e. the portions proximal and distal of the marker).

16. **Claims 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nobuyoshi et al. (5,250,069) in view of Ehr et al. (6,398,709) as applied to claim 1 above, and further in view of Imran et al. (5,766,203).** The combination of Nobuyoshi et al. and Ehr et al. fails to disclose the catheter is a stent delivery catheter. Attention is drawn to Imran et al., who teach a balloon catheter can be used to deliver a stent (figure 8C) to provide permanent support to a weakened vessel. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the catheter of the combination of Nobuyoshi et al. and Ehr et al. as a stent delivery catheter, as taught by Imran et al., to deliver a stent to provide permanent support to a weakened vessel.

17. Regarding claim 23, the stent of Imran et al. is an inflation expandable stent (see column 8, lines 36-41).

18. Regarding claim 24, the Imran et al. stent is self-expanding (column 8, line 56).

19. **Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nobuyoshi et al. (5,250,069) in view of Ehr et al. (6,398,709) as applied to claim 1 above, and further in view of Hamilton et al. (6,514,228).** The combination of Nobuyoshi et al. and Ehr et al. fails to disclose the catheter tip is shaped like a triangle. Attention is drawn to Hamilton et al., who teach an inner catheter tip may have a triangular cross section if desired. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to shape the tip of the combination of Nobuyoshi et al. and Ehr et al. in a triangular shape, as taught by Hamilton et al., as an obvious alternative to the circular catheter shape.

Response to Arguments

20. Applicant's arguments filed 10/12/2010 have been fully considered but they are not persuasive.

21. Applicant argues with respect to the combination of Nobuyoshi et al. and Ehr et al. that one having ordinary skill in the art would not have modified the catheter tip of Nobuyoshi et al. based on the teachings of the guidewire of Ehr et al. However, Examiner contends that since the catheter tip of Nobuyoshi et al. and the guidewire of Ehr et al. are tubular structures, a skilled artisan would have recognized the advantages (namely, increased flexibility of the tubular shaft at the location of the recessed regions) of including recessed portions in the Nobuyoshi et al. catheter tip.

22. Applicant argues with respect to the combination of Fulton and Nobuyoshi et al. that the new claim limitations are not disclosed. However, Examiner notes that applicant has not provided any specific structure required for the newly claimed “coupling” between the catheter shaft distal end and the catheter tip proximal end. The claims only require the "coupling" to be placed somewhere proximal to the balloon. Therefore, some arbitrarily defined location proximal to the balloons of the prior art can be considered the location of the coupling. In the combination, Nobuyoshi et al. are relied upon for the showing of the entrained stiffening fibers. Those fibers extend beneath the proximal waist portion of the balloon (see figure 1 of Nobuyoshi et al.). Since the shaft structure directly beneath the proximal waist portion of the balloon is considered to be part of the second region as outlined above, the claim limitations are met (namely, the stiffening fibers located distal to the coupling).

Conclusion

23. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Examiner notes here that Brisken et al. (2001/0051784) shows at figure 9 the idea that recessed regions (which are capable of acting as balloon storage portions) can be disposed below the proximal and distal cone portions of a balloon. This is evidence to support Examiners position above at paragraph 3.

24. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

25. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to RYAN J. SEVERSON whose telephone number is (571)272-3142. The examiner can normally be reached on Monday - Friday 8:30-5:00.

27. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

28. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ryan J Severson/
Examiner, Art Unit 3731
12/16/10

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773